## JOITOW FORMULAS"

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Orders 800/890-8955
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Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373

## Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

Omega Balance™ is a complex mixture of the biologically active, polyunsaturated lipids Omega 3 from DHA and EPA and Omega 6 from CLA and GLA. These UPUFAs (Ultra Polyunsaturated Fatty Acids) are essential in the synthesis of prostaglandins, which are hormone-like substances critical for cardiovascular and immune health. CLA (Conjugated Linoleic Acid) and DHA synergistically reduce cyclooxygenase, an enzyme involved in inflammation and the formation of ROS (Reactive Oxygen Species) involved in the aging process.

The Omega-3 fatty acids DHA and EPA in Omega Balance™ are from sardine oil, (purified by molecular distillation), the Omega-6 fatty acid GLA is from borage oil, and CLA is made enzymatically from sunflower oil.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:

  Sardine Oil (source of omega-3) [DHA (Docosahexaenoic Acid), EPA (Eicosapentaenoic Acid),

  Stearidonic Acid] GLA (derived from Borage Oil) CLA (Conjugated Linoleic Acid)
- (4) Name of the dietary supplement(s)

Omega Balance<sup>TM</sup> 90 softgels

(5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we wieve to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted.

/Siddharth Shastri, CCN

Vice President, Product Development

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